Introduction of the Implantable Doppler System Did Not Lead to an Increased Salvage Rate of Compromised Flaps

Smit, Jeroen M.; Werker, Paul M. N.; Liss, Anders G.; Enajat, Morteza; de Bock, Geertruida H.; Audolfsson, Thorir; Acosta, Rafael

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Introduction of the Implantable Doppler System Did Not Lead to an Increased Salvage Rate of Compromised Flaps: A Multivariate Analysis

Jeroen M. Smit, M.D.
Paul M. N. Werker, M.D., Ph.D.
Anders G. Liss, M.D., Ph.D.
Morteza Enajat, B.Sc.
Geertruida H. de Bock, Ph.D.
Thorir Audolfsson, M.D.
Rafael Acosta, M.D.

Uppsala, Sweden; and Groningen, The Netherlands

Background: The Cook-Swartz implantable Doppler system was introduced at the Uppsala University Hospital to ease free flap monitoring and improve salvage rates by an earlier detection of vascular compromise. The aim of the current analysis was to investigate whether the system indeed improved the salvage rate of revisions.
Methods: All cases that needed revision among a consecutive series of patients being monitored with the implantable Doppler system between June of 2006 and January of 2009 were compared with a similar set of patients operated on before the introduction of the implantable Doppler system over an equal time span monitored with conventional methods. Data were extracted from the medical files of the patients. Logistic regression was used to identify factors associated with the outcome of the revision. Values of $p < 0.05$ were considered statistically significant.
Results: A total of 327 flaps were monitored with the implantable Doppler system, of which 35 needed revision. In the control group, 303 flaps were included, of which 40 needed revision. The revision was successful in 69 percent of the cases in the implantable Doppler system group; in the group monitored by only conventional methods, this rate was 60 percent. Univariate analysis showed no statistical difference between these success rates ($p = 0.441$; odds ratio, 1.455; 95 percent confidence interval, 0.560 to 3.775). Multivariate analysis did not show a statistical difference either ($p = 0.799$; odds ratio, 1.143; 95 percent confidence interval, 0.410 to 3.182).
Conclusion: The introduction of the implantable Doppler system did not lead to a significant increase in the salvage rate of revised flaps. (*Plast. Reconstr. Surg.* 125: 1710, 2010.)

Since its introduction in the late 1950s,[1] the free flap has evolved into the method of choice as a means of reconstructing large defects. Over the past decade, success rates of 95 percent and higher have been reported.[2–5] Despite these high success rates, complications do occur. They can be divided into general and specific complications. General complications include infection, hematoma, and systemic complications such as pulmonary and cardiac problems. Specific complications are caused by arterial and/or venous occlusion or insufficiency. When such a specific complication occurs and is not acted on fast enough, it will cause necrosis of the flap, either partially or totally.[6,7] To spot these problems in time, flaps are routinely carefully monitored during the early postoperative period to enable reintervention and salvage of the flap.

Conventional monitoring techniques, which are still most commonly used today, include inspection, palpation, capillary refill, handheld Doppler ultrasonography, surface temperature probes, and pinprick tests.[8,9] Adjunctive techniques used to monitor

From the Department of Plastic and Reconstructive Surgery, Uppsala University Hospital, and the Departments of Plastic Surgery and Epidemiology, University Medical Center Groningen, University of Groningen.
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flaps postoperatively include the implantable Doppler system designed by Swartz et al.,[10] near-infrared spectroscopy,[11–13] microdialysis,[14–16] laser Doppler flowmetry[17,18] in some cases combined with tissue spectrophotometry,[19] and modified oxygen microelectrode combined with laser-Doppler flowmetry.[20]

The Cook-Swartz implantable Doppler system was introduced at the Department of Plastic and Reconstructive Surgery of the Uppsala University Hospital in June of 2006 to facilitate free flap monitoring. The goal of its introduction was to ease free flap monitoring and improve salvage rates by an earlier detection of complications. The aim of the current analysis was to investigate whether the system indeed improved the salvage rate of revisions.

PATIENTS AND METHODS

Setting

The Section of Microsurgery of the Uppsala University Hospital, Sweden, consists of three plastic surgeons and a rotating resident. Since 2000, the number of free flaps performed has been approximately 100 per year.

Study Design

All cases among a consecutive series of patients that needed revision being monitored with the implantable Doppler system between June of 2006 and January of 2009 were compared with a similar set of patients (control group) operated on before the introduction of the implantable Doppler system over an equal time span monitored with conventional methods. The groups were compared for the success rate of the revisions.

Patients

In the analysis of revision outcome, only the revised cases were included in which vascular compromise was found during surgery (true-positive readings). Patients undergoing revision but in which no vascular compromise was found during surgery (false-positive readings) were excluded from the analysis. The failed cases in which no revision was undertaken were also included. This was done to prevent bias and the suggestion that we chose to perform fewer revisions in potentially less successful cases to increase our salvage rate.

Monitoring Protocol

All patients went to the intensive care unit directly after surgery. The flap was monitored by trained nursing personnel who were in close contact with the microsurgeon and the anesthesiologist involved. During the first 4 hours after surgery, the flap was checked every 15 minutes. Between 4 and 8 hours after surgery, measurements took place every 30 minutes. After 8 hours, measurements were performed every hour. After the first day, the patient was returned to the ward. On the second day, measurements were taken every 2 hours; on the third day, every 3 hours; and from day 4 until day 7, every 4 hours.

Implantable Doppler System

The Cook-Swartz Doppler Flow Monitoring System (Cook Medical, Cook Ireland Ltd, Limerick, Ireland) consists of an implantable, removable, 20-MHz ultrasonic probe mounted on a silicone cuff that is used to secure the probe around the adventitia of the venous pedicle (Fig. 1). The probe is attached to a wire that exits the body through the incision, where it becomes an external wire attached to the skin by silicone tabs placed around the wire. The external wire can be connected through an extension cable to a portable monitor that provides audible real-time monitoring of venous blood flow. The wire and probe are designed to detach from the silicone cuff with minimal tension, once postoperative vascular monitoring is terminated. Because the flap can often be seen during the monitoring with the implantable Doppler probe, the color of the flap can be used as an adjuvant monitoring method. The system can be of extra value in flaps that are dif-

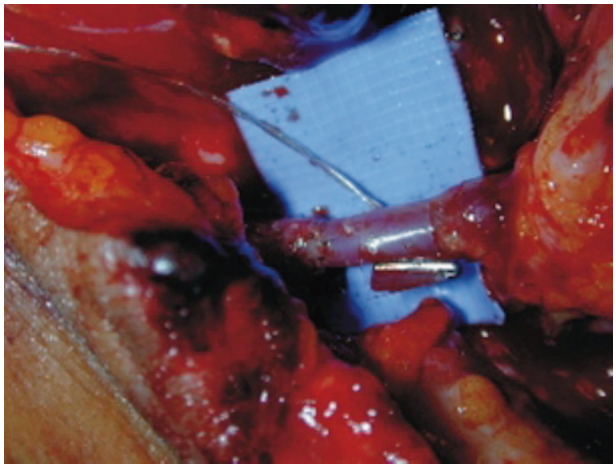

Fig. 1. The silicone cuff with the Doppler crystal wrapped around the vein. The cuff is positioned distal to the anastomoses. The Doppler signal leaves the body through the wire attached to the cuff; this wire can be removed 5 to 10 days after surgery by applying a tension of 50 g. (Courtesy of Cook Medical, Cook Ireland Ltd., Limerick, Ireland.)

ficult to monitor with conventional methods (e.g., buried or muscle flaps).

Conventional Methods

Conventional monitoring methods used were temperature, color, capillary refill, turgor, and handheld Doppler device. The skin temperature was measured continuously. A difference of more than 2°C from the surrounding tissue was considered abnormal. The surrounding tissue of the flap and donor site served as a guideline for the color and turgor. With a handheld Doppler device, the flow was checked. To make the monitoring of buried flaps more reliable, a small skin pedicle was left attached when possible. Intraoral flaps were monitored by only color, turgor, and handheld Doppler assessment.

Data

The following data were collected by reviewing patient files: age, sex, indication for surgery, date of surgery, American Society of Anesthesiologists classification, nicotine use, administration of radiotherapy, location of the defect, type of flap, surgeon, recipient vessels, ischemia time, complications, need for revision, revision indication, and surgical outcome of all patients.

Definitions

Surgical outcome was defined as either success or failure. A successful case was defined as a case in which flap survival was either complete or partial. Failure was defined as complete flap failure. This definition was chosen because the group of partial necroses was too small to use for separate statistical analysis, and it is our vision that partial necrosis is more often attributable to poor flap design than to late detection of a compromised pedicle.

Statistical Analysis

Statistical analysis was performed using SPSS version 16.01 (SPSS, Inc., Chicago, Ill.). The chi-square test and the *t* test were used to compare the characteristics of the implantable Doppler device group with the control group. Logistic regression was used to identify factors associated with the outcome of the revision. The association with each factor was first determined using univariate logistic regression. A value of $p < 0.05$ was considered statistically significant. Apart from the monitoring method used, the following variables were analyzed for their effect on the salvage rate: sex, age, American Society of Anesthesiologists classification, nicotine use, radiotherapy before surgery, location defect, type of flap, surgeon, recipient vessels, and ischemia time. To make sure the subgroups were large enough for a proper analysis (expected value per cell >5), small subgroups were merged. The type of monitoring, and factors with a value of $p < 0.05$, were entered into a multivariate logistic regression model.

RESULTS

Population

In the period reviewed, a total of 630 free microvascular reconstructions were performed; 323 of them were monitored with the implantable Doppler system and 307 were monitored by conventional methods. The overall success rate in the implantable Doppler group was 96.6 percent. In the group monitored by conventional methods, this rate was 94.8 percent (Table 1).

Of flaps that were monitored with the implantable Doppler system, an alteration in the Doppler signal was observed in 38 cases (11.6 percent). In four cases, no further action was undertaken. Of these cases, two were compromised flaps in which the decision was made not to perform any further actions because the chances of success were regarded as minimal on taking the patient characteristics in consideration (these cases are included in the analysis); in one case, there were no other clinical signs of a compromised flap; and in the other case, the patient himself had accidentally removed the wire. A total of 34 cases (10.4 percent) were reoperated on. In one case, the anastomoses were found patent during surgery. This case was excluded from further analysis. The findings during revision were arterial and venous thrombosis ($n = 4$), arterial thrombosis ($n = 12$), arterial inflow insufficiency ($n = 1$), venous thrombosis ($n = 9$), venous congestion ($n = 3$),

Table 1. Characteristics of Reviewed Groups

	Patients Monitored with Implantable Doppler System ($n = 323$)	Patients Monitored by Conventional Methods ($n = 307$)
Location defect		
Breast area	251	197
Head and neck area	39	52
Extremities	33	58
Type of flap		
Cutaneous/fasciocutaneous	283	258
Musculocutaneous	32	33
Osteocutaneous	6	13
Revision rate, %	10.4	12.9
Success rate, %	96.6	94.8

and a hematoma compromising the anastomosis ($n = 4$). In all cases, the alteration in the Doppler signal was either before or at the same time as any clinical signs of flap compromise.

In the group monitored by conventional methods, 39 cases (12.9 percent) were taken back to the operating room because of suspicion of vascular compromise. The findings during revision were arterial and venous thrombosis ($n = 5$), arterial thrombosis ($n = 15$), arterial spasm ($n = 1$), venous thrombosis ($n = 15$), venous congestion ($n = 1$), and a hematoma compromising the anastomosis ($n = 2$). In one case, no revision was undertaken for a failing flap, because the compromise was found in a relatively late phase. This case was included in the analysis as well (Table 2).

Characteristics of the Patients under Study

In the revised group that was monitored by the implantable Doppler system, the mean age was 49.1 ± 12.5 years (range, 26 to 85 years). The mean American Society of Anesthesiologists classification was 1.7 (four patients were treated for hypertension and two had diabetes). The reconstructions performed were breast reconstructions, flaps to extremities, and head and neck cases in 69, 17, and 14 percent, respectively. In the revised group that was monitored with conventional methods, the mean age was 46.8 ± 14.3 years (range, 8 to 80 years). The mean American Society of Anesthesiologists classification was 1.9 (two patients were treated for hypertension, two had diabetes, and one used corticosteroids). The reconstructions carried out were breast reconstructions, flaps to extremities, and head and neck cases in 58, 27, and 15 percent, respectively (Tables 3 and 4).

Statistical comparison of the groups only revealed significant differences on the items "senior surgeon" and "use of nicotine." More cases in the group monitored by the implantable Doppler system were operated on by the senior author (R.A.), and significantly more patients smoked at the time of admission in the conventional monitoring methods group.

Table 2. Cases Included in Analysis

	Patients Monitored with Implantable Doppler System	Patients Monitored by Conventional Methods
Arterial and venous thrombosis	4	5
Arterial thrombosis	12	15
Arterial insufficiency	1	—
Arterial spasm	—	1
Venous thrombosis	9	15
Venous congestion	3	1
Hematoma	4	2
Failed flap, no revision undertaken	2	1
Total	35	40

Success Rate Revisions for Each Monitoring Method

The revision was successful in 69 percent of the cases in the implantable Doppler system group. Thirty-one percent of the flaps failed. In the group that was monitored by only conventional methods, 60 percent of the flaps could be salvaged with the help of a revision, and 40 percent of them failed. Univariate analysis showed no statistical difference between these success rates ($p = 0.441$; odds ratio, 1.455; 95 percent confidence interval, 0.560 to 3.775).

Multivariate Analysis

The variables "location defect" and "radiotherapy before surgery" showed a statistically significant difference (Table 5) and were put in the multivariate analysis together with "the monitoring method used." The multivariate analysis showed no statistical differences between the groups (Table 6). A strong tendency was shown between the salvage rate and location of the defect, meaning revisions in the breast reconstructions were more likely to be successful compared with reconstructions elsewhere.

DISCUSSION

A total of 36 flaps were included in the implantable Doppler group, whereas in the group monitored with conventional methods, 40 were included. We found that the success rate of the revised flaps increased from 60 percent to 69 percent after the introduction of the implantable Doppler system. However, this difference is not significant. The multivariate analysis in both groups showed a strong association between the location of the defect and the outcome of the revision: the chance of a successful revision is larger in a breast reconstruction as compared with a head and neck or extremity case.

A number of previous reports have also addressed the value of the implantable Doppler system.[21–26] In the report by Kind et al.,[23] their

Table 3. Characteristics of Revised Cases for Each Monitoring Method

Characteristic	Patients Monitored with Implantable Doppler System ($n = 35$)	Patients Monitored by Conventional Methods ($n = 40$)	p
Sex			
Male	9	7	0.386
Female	26	33	
Mean age, yr	49.1	46.8	0.456
ASA classification			
I	14	12	0.364
II or more	21	28	
Nicotine use			
Yes	1	11	0.004
No	34	29	
Radiotherapy before surgery			
Yes	17	12	0.099
No	18	28	
Location defect			
Head and neck	5	6	0.534
Breast	24	23	
Extremities	6	11	
Type of flap			
Fasciocutaneous	31	32	0.312
Other (musculocutaneous, osteocutaneous)	4	8	
Surgeon			
R. Acosta	26	24	0.003
Other	9	16	
Recipient vessel			
Internal mammary artery	23	18	0.072
Other	12	22	
Mean ischemia time, min	74.2	87.9	0.095

ASA, American Society of Anesthesiologists.

Table 4. Flaps Used for Each Monitoring Group

Origin of Flap	Patients Monitored with Implantable Doppler System ($n = 35$)	Patients Monitored by Conventional Methods ($n = 40$)
DIEP	14	17
S-GAP	5	6
SIEA	5	—
Anterolateral thigh	4	2
Radialis	2	2
Lateral arm	—	5
Latissimus dorsi	3	3
Fibula	1	3
Other (scapular, gracilis, serratus)	1	2

DIEP, deep inferior epigastric perforator; S-GAP, superior gluteal artery perforator; SIEA, superficial inferior epigastric artery.

experience with the implantable Doppler system was analyzed in 147 cases. After the introduction of the probe, the success rate of revisions increased from 71 percent to 100 percent, and they claimed this increase in successful salvage rates to be significant. However, this was not substantiated by statistical tests. In the other reports, the authors only share their experience with the probe and its reliability, without discussing how it affected the salvage rate of their compromised flaps. Although all reports are positive about the ability of the implantable Doppler system to detect a compromised flap,[22–26] an important downside of some reports is the high rate of false-positive readings[21,24,25] of the system of up to 88 percent. If false-positive readings are not recognized at an early stage, this could lead to an unnecessary revision and an increase in costs.

The results of our study surprised us to some extent, because we anticipated a beneficial effect of the new monitor device. Inflow or outflow disturbance initiates a cascade of events that sooner or later leads to changes in the outer aspect of the flap (color, temperature, refill), which are the subject of conventional monitoring methods. Therefore, we expected that with the introduction of the implantable Doppler system the signaling would improve, leading to earlier intervention with more favorable outcomes. A possible explanation for this is that our monitoring with conventional methods was already of good quality and therefore the introduction of the implantable Doppler system led to only a marginal improvement. In units that experience more problems with conventional monitoring, the introduction of the implantable Doppler system may have a larger effect. To an-

Table 5. Univariate Analysis of Potential Factors Associated with Success Rate of the Revisions

Variable	Successful Revision ($n = 48$)	Unsuccessful Revision ($n = 27$)	p	Odds Ratio	95% Confidence Interval
Monitoring method					
Implantable Doppler system	24	11	0.441	1.455	0.560–3.775
Conventional methods	24	16			
Sex					
Male	10	6	0.888	0.921	0.293–2.891
Female	38	21			
Mean age, yr	46.6	50.2	0.278	0.980	0.946–1.016
ASA classification					
I	20	6	0.094	2.500	0.855–7.314
II of more	28	21			
Radiotherapy before surgery					
Yes	23	6			
No	25	21	0.032	3.220	1.105–9.383
Nicotine use					
Yes	5	7	0.088	0.332	0.094–1.176
No	43	20			
Location					
Breast	35	15	0.016	3.365	1.250–9.063
Other (head and neck, extremities)	13	12			
Type of flap					
Fasciocutaneous	42	21	0.276	2.000	0.575–6.959
Other (musculocutaneous, osteocutaneous)	6	6			
Surgeon					
R. Acosta	27	15	0.954	1.029	0.398–2.658
Other	21	12			
Recipient vessel					
Internal mammary artery	30	11	0.072	2.424	0.982–6.362
Other	18	16			
Mean ischemia time, min	79.1	88.9	0.314	0.994	0.982–1.006

ASA, American Society of Anesthesiologists.

Table 6. Multivariate Analysis of Potential Factors Associated with Success Rate of the Revisions

Variable	p	Odds Ratio	95% Confidence Interval
Monitoring by implantable Doppler system	0.799	1.143	0.410–3.182
Defect located at breast area	0.056	2.721	0.973–7.612
Received radiotherapy before surgery	0.112	2.487	0.808–7.657

swer this, a multicenter, randomized, controlled study has to be performed, including centers with different levels of experience in monitoring. This study can include all type of flaps or only a specific group. In our center, the greatest advantage of the implantable Doppler system was experienced in the head and neck cases.

In this study, a failure rate of salvages of 31 and 40 percent was reported. In a post hoc power analysis, 450 patients per group would be needed to achieve 80 percent power to detect this 9 percent difference given a significance level of 5 percent. It can be questioned whether a statistical difference given these numbers might be clinically different.

When introducing a new system into clinical practice, a learning curve always needs to be respected. In our case, the learning curve was relatively uneventful. This may be attributable to a thorough introduction of the system for medical and nursing staff. An important aspect when working with the system is how to place the wire in the wound. Because the Doppler crystal can be easily dislodged from the silicone cuff (only a tension of 50 g is required), we make sure that the wire is absolutely slack inside the wound. We achieve this by coiling the wire around a forceps (Fig. 2), to give it a spiral shape. In this way, any tension on the wire is not transferred directly to the junction between the wire and the silicone cuff. This safety measure may explain our relatively low false-positive rate of 8 percent.

The case in the implantable Doppler system group in which an unnecessary revision was performed was a bilateral deep inferior epigastric perforator breast reconstruction in which the signal did not stop but altered in one flap. Because there were also some clinical signs suggesting anastomotic problems, the patient was taken back to the operating room. Inspection during revision, however, did not show an anastomotic problem, and no further problems occurred with the flap.

Although in this case the threshold was low to take the patient back to the operating room, in

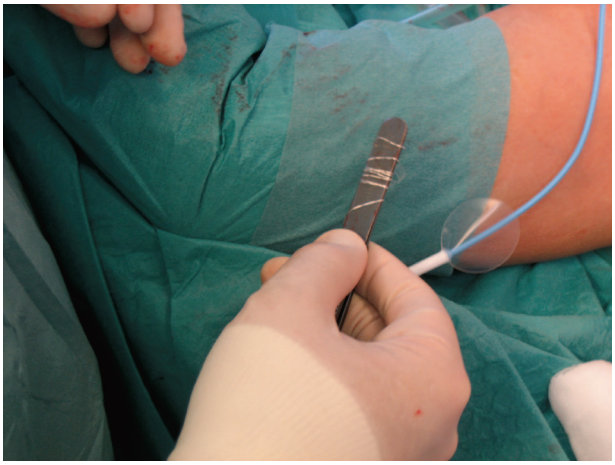

Fig. 2. The wire of the implantable Doppler system is being coiled around a forceps to ensure that, after inset of the flap, tension on the external wire is not being transferred directly to the junction between the wire and the silicone cuff.

recent years, we have become more critical about attempting to perform revision in the first place. In some, already during the initial reconstruction, it may be impossible to achieve or maintain good circulation through the flap. In such cases, we now have adopted the strategy of aborting the reconstruction and removing the flap instead of performing two or three unsuccessful salvage procedures. These flaps in our series have nevertheless been scored as failures; however, this was not related to the time point of reintervention.

When comparing the implantable Doppler system with the conventional monitoring methods group, criticisms include the fact that the group monitored with just conventional methods contains more smokers and that there is a statistical difference attributable to the senior surgeon operating on the case. The difference in nicotine use is related to the difference in study populations. The group monitored with conventional methods includes relatively more head and neck and extremities cases, which are operated on more acutely, making it impossible to select patients with regard to their smoking habits. If possible, we want our patients to stop smoking at least 2 months before surgery, because it has been shown that smoking can decrease the chances of a successful reconstruction.[27] The difference in surgeon can be explained by a change in our team: in 2006, one of the senior surgeons left our department. Although these variables differ between the groups, our analysis did not show that one of these variables had a significant influence on the salvage rate of the revised cases.

When comparing newer monitoring methods, such as the implantable Doppler system, with conventional methods, one of the issues is the cost. Ideally, a new monitoring system should offer a return on investment by saving a higher number of flaps, cost an insignificant amount compared with the total expenditure, or offer nonfinancial benefits. The cost of a free flap at Uppsala University Hospital is €25,000, whereas each disposable probe costs €330 and the monitoring box costs €2650, which is a one-time investment, and costs less than €10 in each case in this series. This is a 1.4 percent increase in costs compared with conventional methods. As far as the nonfinancial benefits are concerned, although not strictly investigated, it can be said that the system has been very well perceived by medical and nursing staff. Compared with conventional monitoring methods, it has been found to be easier to interpret, especially for those not so familiar with free flap monitoring. In addition, the system offers more patient comfort. Monitoring can be accomplished without waking up the patient at night. Finally, because of its direct and continuous monitoring, it offers valuable information during the early reperfusion phase intraoperatively and during the positioning of the patient postoperatively.

Based on these findings, we still find the extra investment of the implantable Doppler system worthwhile. We have planned a prospective study to further explore the ease-of-use aspects of the system.

CONCLUSIONS

After introduction of the implantable Doppler system, the salvage rate of our flaps did not improve statistically significantly. Despite this, its addition to the care of our patients was judged as a positive innovation in free flap monitoring by medical and nursing staff and by patients because of its ease of use and the information it offers.

Rafael Acosta, M.D.
Department of Plastic and Reconstructive Surgery
Uppsala University Hospital
SE-751 85 Uppsala, Sweden
rafael.acosta.rojas@akademiska.se

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